## **REMARKS/ARGUMENTS**

Reconsideration and continued examination of the above-identified application are respectfully requested.

The amendments to the claims and specification are editorial in nature. Full support for the amendment can be found throughout the present application, for instance, at page 17 of the specification. The scope of claims has not been altered by this amendment. Accordingly, no questions of new matter should arise, and entry of the amendment is respectfully requested.

With respect to the restriction requirement, the applicant believes that the non-elected subject matter should be examined at this time, namely the subject matter of claims 24-31 drawn to a sodium zirconium carbonate. While the compositions are not identical, they are both zirconium based and as indicated by the Examiner, they are classified in the same class and only differ with respect to the sub-class. Under MPEP §803, if there is no serious burden on the part of the Examiner to search the entire claimed subject matter, the Examiner must proceed with searching the entire subject matter even if the subject matter is directed to several inventions. Accordingly, the Examiner is respectfully requested to withdraw the restriction requirement and to proceed with examination of all of the claims. In the meantime, the applicants confirm the election with traverse to prosecute the invention of Group II encompassed by claims 35-51.

Claims 35-51 are pending in the present application. Claims 1-23 and 32-34 have been canceled previously. Claims 24-31 have been withdrawn.

At page 3 of the Office Action, the Examiner rejects claims 35-42 under 35 U.S.C. § 103(a) as being unpatentable over JP 362226807 A (JP '807) in view of JP 359069428 A (JP '428). According to the Examiner, JP '807 describes a method for producing zirconium phosphate by heating a mixture of zirconium oxide and phosphoric acid. The Examiner asserts that JP '807 does

not teach that the zirconium oxide is formed by treating sodium zirconium phosphate with caustic soda, as recited in claims 35-42 of the present application. However, the Examiner asserts that JP '428 describes a method for producing zirconium oxide by heating an alkaline aqueous solution containing zirconium carbonate. Thus, the Examiner concludes that it would have been obvious that the alkaline agent in the process of JP '428 could be caustic soda. Furthermore, the Examiner states that it would be obvious to form the zirconium oxide required for the process of JP '807 by the process described in JP '428. For the following reasons, this rejection is respectfully traversed.

Claim 35 recites a method of making zirconium phosphate by treating sodium zirconium carbonate with caustic soda to form alkaline hydrous zirconium oxide; heating a slurry, including the alkaline hydrous zirconium oxide, and adding phosphoric acid; and recovering the zirconium phosphate.

JP '807 describes a method to produce "crystalline layer zirconium phosphate" by allowing a zirconium oxide to react with a phosphoric acid. Additionally, JP '428 describes a method to manufacture ultrafine powder of zirconium oxide by heating an alkaline aqueous solution containing zirconium carbonate under pressure. However, JP '428 does not teach or suggest that its zirconium carbonate is a <u>sodium</u> zirconium carbonate. Even the formulas in the actual JP reference, to the extent readable, do <u>not</u> show <u>sodium</u> zirconium carbonate, only the hydrogen form. Furthermore, JP '428 does not teach or suggest the addition of <u>caustic soda</u> to any <u>sodium</u> zirconium carbonate. In fact, to produce zirconium oxide, JP '428 only describes heating an alkaline aqueous solution having zirconium carbonate. JP '428 does not teach or suggest how the alkaline aqueous solution containing zirconium carbonate is formed. In fact, the text of JP '428 at page 148 only describes and illustrates creation of zirconium oxide by the formula H<sub>2</sub>ZrO (CO<sub>3</sub>)<sub>2</sub> → ZrO<sub>2</sub> + 2CO<sub>2</sub> + H<sub>2</sub>O. Claim 35 of the present invention specifically recites <u>sodium</u> zirconium carbonate and the

use of caustic soda therewith.

It is important for the Examiner to also appreciate that although the ZrP synthesized through the SZC route, as recited in the claimed invention, does not include a pure crystalline structure and is mainly amorphous, the adsorption quality for ammonia and metal ions is equivalent to that of pure crystalline ZrP, and is far superior to that of ZrP derived from zirconium oxide, as described in JP '807 and JP '428. The superior adsorption quality for ammonia and metal is due to the more abundant Zr-OH groups in the alkaline hydrous zirconium oxide which makes the reaction with phosphoric acid more complete than Zr-O in the zirconium oxide resulting in more homogeneous structure and composition of product with higher porosity and internal surface area.

Therefore, JP '428 does not teach or suggest forming an alkaline hydrous zirconium oxide by treating sodium zirconium carbonate with a caustic soda, as recited in claim 35 of the present application. Further, the subject matter of claims 36-42 is not shown in either Japanese reference. Thus, the combination of JP '807 and JP '428 does not teach or suggest the claimed invention. Accordingly, this rejection should be withdrawn.

At page 4 of the Office Action, the Examiner rejects claims 43-45 under 35 U.S.C. § 103(a) as being unpatentable over JP '807 in view of JP '428 and further in view of Pospelova et al. According to the Examiner, Pospelova et al., at page 997, describes forming the sodium zirconium phosphate required in the process of JP '428 by heating zirconium oxychloride with soda ash. For the following reasons, this rejection is respectfully traversed.

Claim 43 of the present application, which is dependent on claim 35, recites that a sodium zirconium carbonate is obtained from heating zirconium oxychloride with soda ash at a sufficient temperature and for a sufficient time to form the sodium zirconium carbonate. Furthermore, claim 44 recites that the heating of zirconium oxychloride is at a temperature of from about 150° F to

about 250° F.

The arguments set forth above with respect to JP '807 in view of JP '428 apply equally here. The JP references do not teach or suggest the use of sodium zirconium carbonate, nor the use of caustic soda.

Pospelova et al. does not provide these deficiencies. According to Pospelova et al., a concentrated zirconium oxide chloride solution is added to hot, saturated sodium carbonate. Accordingly, one skilled in the art, by reading Pospelova et al., would know that the formation of SZC in Pospelova et al. is rapid at high-mixing temperatures, which forms an amorphous and jelly-like product, i.e., containing an abundance of OH groups with low surface area and a wide range of particle size.

Given that Pospelova et al. describes a method for making <u>sodium</u> zirconium carbonate, and JP '428 relates to an alkaline aqueous solution containing zirconium carbonate, one skilled in the art would not look to Pospelova et al. for making the zirconium carbonate of JP '428. The products are different. Zirconium carbonate is not the same compound as sodium zirconium carbonate.

Furthermore, since JP '428 does not suggest that the zirconium carbonate can be substituted with other compositions, such as sodium zirconium carbonate, one skilled in the art would not be motivated to combine the two references.

With respect to claim 44, Pospelova et al. does not teach or suggest heating the mixture at a temperature of from about 150° F to about 250° F. Accordingly, one skilled in the art would not combine JP '428 with Pospelova et al. Even if the references were combinable, the combination of the references does not teach or suggest the claimed invention. Accordingly, this rejection should be withdrawn.

At page 4 of the Office Action, the Examiner rejects claims 46-51 under 35 U.S.C. § 102(b)

as anticipated by or, in the alternative, under 35 U.S.C. § 103(a), as being obvious over JP '807. The Examiner states that the zirconium phosphate formed according to the process of JP '807 would inherently have the properties that are recited in claims 46-51. For the following reasons, this rejection is respectfully traversed.

Claim 46 recites a zirconium phosphate having a Na<sup>+</sup> wt.% of from about 4 wt.% to about 6 wt.%; a ZrO<sub>2</sub> wt.% of from about 34 wt.% to about 37 wt.%; a PO<sub>4</sub> wt.% of from about 41 wt.% to about 43 wt.%; and a H<sub>2</sub>O wt.% of from about 14 wt.% to about 18 wt.%, based on the weight of the zirconium phosphate.

According to the Examiner's conclusion, any mixture concentration of zirconium oxide with phosphoric acid will produce the same weight percent of Na<sup>+</sup>, ZrO<sub>2</sub>, PO<sub>4</sub>, and H<sub>2</sub>O recited in claim 46 of the present application. The Examiner's conclusion is simply incorrect. The weight percentages recited in claim 46 are produced when a predetermined concentration of zirconium oxide is added to a predetermined concentration of phosphoric acid, at a predetermined amount, temperature, time, and other predetermined parameters. A change of a single parameter can vary the concentrations recited in claim 46. JP '807 simply does not teach or suggest the concentrations recited in claim 46 of the present application. Moreover, no source of Na+ is described in JP '807. So, how can JP '807 possibly teach a sodium content?

It is important for the Examiner to appreciate that ZrP synthesized through the SZC route has a controlled particle size range (30-40 microns) as described in the specification of the present application and as recited in claim 51. The controlled particle size range is the result of the controlled particle growth reaction of SZC. The controlled particle size is considered important for sorbent dialysis. Furthermore, none of the methods described in the cited references can produce a ZrP of a suitable particle size for column application.

Furthermore, unlike the methods described in the cited references, the ZrP of the claimed invention includes 4 wt.%—6 wt.% sodium. The sodium content helps to increase the adsorption capacity of the ZrP for ammonia and other metal ions due to ion-exchange. At the same time, the sodium content also helps to suppress the hydrogen ion content of the material, thereby providing a pH range that is suitable for dialysis. In contrast, the ZrP described in the cited references is in the hydrogen/acid form with no sodium content. Therefore, the ZrP of the cited references includes a lower adsorption capacity than the adsorption recited in claim 47 of the present application. Furthermore, as described in the present application, sodium is introduced to ZrP and is regulated to 4–6 wt% by titrating the acid ZrP slurry with caustic soda to obtain a pH of from about 5 to about 6. Given that ZrP is an ion-exchange material, the sodium from caustic soda simply replaces the hydrogen ion from the material, which is then neutralized by the base. The combination of the references simply does not teach or suggest a sodium content. Accordingly, this rejection should be withdrawn.

Also, at page 4 of the Office Action, the Examiner rejects claims 46-51 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a), as obvious over either Alberti et al. (U.S. Patent No. 4,826,663) or Nowell et al. (U.S. Patent No. 4,381,289). The Examiner asserts that Nowell et al., at column 1, lines 22-32, states that the zirconium phosphate can selectively remove ammonium and heavy metal ions from solutions by ion exchange, and Alberti et al., at column 3, lines 14-22, describes that the zirconium phosphate quickly exchanges such large-sized ions as cesium and barium. For the following reasons, this rejection is respectfully traversed.

With respect to Alberti et al. and Nowell et al., neither of the two references teaches or suggests the wt.% recited in claim 46 of the present application. Accordingly, the Examiner cannot

conclude that the zirconium phosphate recited in Alberti et al. or Nowell et al. is the same or equivalent to the zirconium phosphate recited in claim 46 of the present application. The ZrP described in Alberti et al. and Nowell et al. is highly crystalline ZrP prepared under drastic conditions with a composition (especially Na%), particle size, and crystal structure that are quite different from the claimed invention. The specific examples of Nowell et al. show no Na<sup>+</sup> in the zirconium phosphate formed. This is equally true for all of the examples of Alberti. Contrary to the inherency position of the Examiner, the zirconium phosphate of the presently claimed invention is chemically different and inherency is not an issue. It is also questionable whether the other parameters of the claims are shown in the cited references as well. Accordingly, this rejection should be withdrawn.

At the bottom of page 4 of the Office Action, the Examiner rejects claims 35-51 under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner asserts that claim 35 does not include an antecedent basis for the phrase, "said acid zirconium phosphate." Furthermore, the Examiner states that claim 46 is indefinite because the unit of Na content is not determined. More specifically, the Examiner states that it is not clear whether the Na content is based on weight percent or molar percent. Additionally, with respect to claim 47, the Examiner states that the recitation of "ANSI/AAMI RD-5-1992" is indefinite, since the standard is subject to change. For the following reasons, this rejection is respectfully traversed.

Claim 35 has been amended to address proper antecedent basis for the term "acid zirconium phosphate."

Claim 46 now recites that the sodium content is in weight percent. Full support for the sodium content being in weight percent exists at page 17 of the present specification.

Claim 47 specifically recites, in part, that the zirconium phosphate satisfies the standard on extractable toxic impurities as set forth under ANSI/AAMI RD-5-1992. Although the ANSI/AAMI standard may change from one year to another, claim 47 clearly indicates that the ANSI/AAMI standard recited in the claim is based on the 1992 ANSI/AAMI standard. Accordingly, the phrase, "ANSI/AAMI RD-5-1992," is definite, since one skilled in the art, by reading ANSI/AAMI RD-5-1992, would refer to the ANSI/AAMI standard set forth in 1992. It is well known to one skilled in the art that the standard does not continuously change within a particular year. Accordingly, this rejection should be withdrawn.

At page 5 of the Office Action, the Examiner rejects claims 46-51 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. More specifically, the Examiner states that the specification does not enable one skilled in the art to form a zirconium phosphate having a sodium content of from about 4 to about 6 wt.%. For the following reasons, this rejection is respectfully traversed.

The process for obtaining the zirconium phosphate of the claimed invention, which can include from about 4 to about 6 wt.% Na<sup>+</sup>, from about 34 to about 37 wt.% ZrO<sub>2</sub>, from about 41 to about 43 wt.% PO<sub>4</sub>, and from about 14 to about 18 wt.% H<sub>2</sub>O, is clearly recited, for instance, at pages 16, 17, and Example 2 of the present application as well as the claims as originally filed. Furthermore, to re-emphasize, Na<sup>+</sup> is introduced to ZrP and is regulated to 4–6% by titrating the acid ZrP slurry with caustic soda to obtain a pH of from about 5 to about 6. Given that ZrP is an ion-exchange material, the sodium from caustic soda replaces the hydrogen ion from the material, which is then neutralized by the base. The Examiner provides no technical reasoning to justify his

opinion, and yet the present invention provides significant detail and an example of the making of the ZrP. Clearly, enablement exists to one skilled in the art. Accordingly, this rejection should be withdrawn.

The Examiner is respectfully requested to contact the undersigned by telephone should there be any remaining questions as to the patentability of the pending claims.

## **CONCLUSION**

In view of the foregoing remarks, the applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

Luke A. Kilyk

Reg. No. 33,251

Atty. Docket No. 3191-003-01 KILYK & BOWERSOX, P.L.L.C. 53 A East Lee Street

Warrenton, VA 20186 Tel.: (540) 428-1701 Fax: (540) 428-1720